



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4844]

“Ruby Chocolate” Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a temporary permit has been issued to Barry Callebaut U.S.A. LLC (the applicant) to market test a product identified as “ruby chocolate” that deviates from the U.S. standards of identity for chocolate products. The temporary permit will allow the applicant to evaluate commercial viability of the product and to collect data on consumer acceptance of the product.

DATES: This permit is effective for 15 months, beginning on the date the applicant introduces or causes introduction of the test product into interstate commerce, but not later than [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION: We are giving notice that we have issued a temporary permit to Barry Callebaut U.S.A. LLC. We are issuing the temporary permit in accordance with 21 CFR 130.17, which addresses temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

The permit covers the interstate market testing of the product identified as “ruby chocolate.” The test product deviates from the U.S. standards of identity for chocolates (21 CFR 163.111, 163.123, 163.124, 163.130, 163.135, 163.140, and 163.145).

For the purpose of this permit, “ruby chocolate” is the solid or semiplastic food prepared by mixing and grinding cacao fat with one or more of the cacao ingredients (namely, chocolate liquor, breakfast cocoa, cocoa, and lowfat cocoa), citric acid, one or more of optional dairy ingredients, and one or more optional nutritive carbohydrate sweeteners. “Ruby chocolate” contains not less than 1.5 percent nonfat cacao solids, not less than 20 percent by weight of cacao fat, not less than 2.5 percent by weight of milk fat, not less than 12 percent by weight of total milk solids, not more than 1.5 percent of emulsifying agents, and not more than 5 percent of whey or whey products. It may also contain other ingredients such as antioxidants approved for food use, spices, natural and artificial flavorings, and other seasonings. However, these other ingredients cannot imitate the flavor of chocolate, milk or butter, berry or another fruit. Additionally, “ruby chocolate” contains no added coloring. The test product “ruby chocolate” contains the principal ingredients used in most of the current standards for cacao products under 21 CFR part 163; however, it deviates from the current standards of identity for chocolate products in terms of its final composition, taste, and color.

The purpose of the temporary permit is to allow the applicant to market test the product throughout the United States. The permit will allow the applicant to evaluate commercial viability of the product and to collect data on consumer acceptance of the product.

The permit provides for the temporary marketing of approximately 60 million pounds (27,215,540 kilograms) of the test product. The test product will be manufactured at the Barry

Callebaut facilities located at Aalstersestraat 122, 9280 Lebbeke, Belgium; 400 Industrial Park Rd., St. Albans, VT 05478; and 1175 Commerce Blvd., American Canyon, CA 94503.

Barry Callebaut U.S.A. LLC will distribute the test product to various manufacturers throughout the United States for further manufacturing and market testing. Each ingredient used in the food must be declared on the label as required by 21 CFR part 101. The permit is effective for 15 months, beginning on the date the applicant introduces or causes the introduction of the test product into interstate commerce, but not later than [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: November 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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